

UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

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SUBCOMMITTEE 1

ISSUE I: WITHIN ESTABLISHMENT INSPECTION

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February 6, 2008

1:15 p.m.

Key Bridge Marriott  
Arlington, Virginia

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Minnesota Department of Agriculture

COMMITTEE MEMBERS:

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MS. CHERYL D. JONES  
DR. EDNA NEGRON-BRAVO  
DR. MICHAEL L. RYBOLT  
MR. MARK SCHAD  
DR. STANLEY STROMBERG

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1 P-R-O-C-E-E-D-I-N-G-S

2 (1:15 p.m.)

3 MR. ELFERING: Carol Tucker-Foreman will be  
4 joining us by telephone, and hopefully she will be on  
5 the line shortly. I'll just get started with a  
6 little bit of introductory information first.

7 This is Subcommittee Number 1, and we're  
8 going to be discussing within establishment  
9 inspection system.

10 Before we start, I think I'll have all the  
11 Committee members introduce themselves. I'm Kevin  
12 Elfering. I'm the Subcommittee Chair.

13 MR. SCHAD: Mark Schad.

14 MS. NEGRON-BRAVO: Edna Negron.

15 DR. RYBOLT: Michael Rybolt.

16 DR. STROMBERG: Stan Stromberg.

17 MR. ELFERING: Hopefully, I'll have a copy  
18 of the issue that we're going to be discussing, Issue  
19 Number 1, and again I'd like to reiterate for those  
20 of you in the audience from consumer groups, industry  
21 or anyone else who is interested in food safety, feel  
22 free to participate in our discussion. You can join

1 us up at the table here. All I ask is if you do have  
2 any comments that you identify yourself before you  
3 make any comments.

4 We also have some subject matter experts  
5 from USDA FSIS. Would you like to introduce  
6 yourselves as well?

7 MR. SMITH: Bill Smith, OPEER.

8 DR. MACZKA: Carol Maczka, Office of Food  
9 Defense.

10 DR. TRAVIS: Curtis Travis, SAIC.

11 DR. DREYLING: Erin Dreyling, with the Data  
12 Analysis and Integration Group.

13 DR. ARRINGTON: Isabel Arrington, Office of  
14 Policy.

15 MR. ELFERING: What we're going to be doing  
16 is I'm going to read the issue, and then we'll talk  
17 about the questions, and then I think what we're  
18 going to do is just take them maybe one at a time.  
19 We have two different types of products that we're  
20 going to be discussing, we'll kind of -- I'll read  
21 the issue first of all.

22 The problem definition is in the proposed

1 Public Health Risk-Based Inspection System, FSIS will  
2 focus its verification activities on points within  
3 processing and slaughter establishments that have the  
4 greatest potential for microbial contaminations or  
5 growth if process control is not maintained  
6 (vulnerable points). This approach first within the  
7 current regulatory framework and is linked to  
8 inspectors carrying out their existing inspection  
9 procedures related to HACCP, SSOPs and SPS.

10 FSIS would like the National Advisory  
11 Committee's comments on the proposed within  
12 establishment inspection system. It is suggested  
13 that the Committee focus on the prompts for poultry  
14 slaughter which is PBIS code, I'm sure is 03J and  
15 fully cooked not shelf-stable products which is  
16 called 03G when responding to the questions below.  
17 The committee may choose other prompts to focus on,  
18 if it better suits the background of Committee  
19 members. Specifically, the Committee should consider  
20 the following questions in its discussion:

21 1. What recommendations does the Committee  
22 have regarding how to better use and identify the

1 prompts identified for the within establishment  
2 inspection system.

3 2. What recommendations does the Committee  
4 have with the design of the vulnerable points  
5 identified for the within establishment system?

6 And I think what we'd like to do is first  
7 of all work on the fully cooked, not shelf stable  
8 products, and for information on the prompts, they  
9 are in one of the appendices. It's Appendix B under  
10 Tab 5, and it starts on page B-47. And I think what  
11 we can probably do is if anybody has any opening  
12 comments that they'd like to make, otherwise, we can  
13 kind of take these prompts one by one and discuss  
14 them.

15 (No response.)

16 MR. ELFERING: I'm not hearing any, so why  
17 don't we start with the vulnerable points that they  
18 have identified is receiving and storing and  
19 processing which include mixing, formulating,  
20 grinding, tempering, molding, solution injection,  
21 rework without a step in stabilization, and also we  
22 said receiving and storing -- and then post-lethality

1 processes, for example, slicing, peeling and  
2 packaging.

3 So first of all, maybe we should discuss  
4 receiving and storing relating to the questions, is  
5 what recommendations does the Committee have  
6 regarding how to better use and identify prompts?  
7 And then also any concerns with the design of the  
8 vulnerable points.

9 So for receiving and storage, is there any  
10 discussion on receiving and storage?

11 MS. TUCKER-FOREMAN: Kevin, Kevin, can you  
12 hear me?

13 MR. ELFERING: We certainly can. I --  
14 Carol, I just kind of went over the issues, and we're  
15 just -- went over the prompts that FSIS has  
16 identified, the receiving and storage processing and  
17 post-lethality. We're working on the fully cooked,  
18 not shelf stable. And that's in Appendix B, page 47,  
19 it starts on.

20 MS. TUCKER-FOREMAN: Now, Kevin, I have the  
21 paper and it really seems to me that the Agency has  
22 -- is implementing this enormous change in inspection

1 and they're asking us to address two really not very  
2 significant issues. I, I would urge the Subcommittee  
3 to consider kind of redefining the questions and  
4 trying to respond to bigger questions that are out  
5 here. Obviously I'll refer to the Subcommittee but  
6 it just really seems silly to me to spend the time  
7 talking about prompts when we've got massive change  
8 in poultry slaughter inspection proposed.

9 MR. ELFERING: Well, I think that's one of  
10 the things that we probably will be discussing and I  
11 think one of the issues that we have, you know, we  
12 are not always going to necessarily agree with the  
13 questions that they pose in front of us but I think  
14 that that is the opportunity that we have is where we  
15 think the focus should be. So, I think that this is  
16 normally a part of this process.

17 MS. TUCKER-FOREMAN: Well, I certainly  
18 agree with you. I don't think this is where our  
19 attention ought to be. So I'll be quiet for a while.

20 DR. RYBOLT: I have a question -- but are  
21 we -- is it our intention to go through each one,  
22 like -- we'll go through each one of the prompts,

1 look at the question and -- or maybe the Agency can  
2 answer this. What specifically are you looking for  
3 in regards to this series of questions from the  
4 Subcommittee?

5 MR. ELFERING: Yeah, I think that's good.  
6 Really, and that is what are you really trying to,  
7 trying to determine?

8 DR. DREYLING: I mean I think we wanted --  
9 first of all -- Yeah, I think it's one. That's  
10 okay. We would like comments just on the overall  
11 nature of the questions. Do you think that they're  
12 worded properly? Do you think that they're too  
13 prescriptive? Do you agree with that? Then if -- we  
14 don't need you to go through every single question I  
15 mean unless there are certain things that would stand  
16 out to certain Committee members that they don't  
17 agree with or they think is not a proper question on  
18 there. But I think we're looking for bigger picture  
19 questions about the prompts, and we want -- we gave  
20 you two specific examples because we thought that  
21 would be a little bit easier to deal with than saying  
22 comment on all of our prompt questions.

1 DR. RYBOLT: As a follow-up to that, and  
2 maybe a suggestion, that maybe the Subcommittee won't  
3 consider, but these were developed within FSIS with  
4 FSIS identified experts. Has the Agency or will the  
5 Agency go outside to, you know, I don't want to say  
6 expert elicitation. I don't want to bring that up  
7 again but, you know, go outside and find some other  
8 food safety experts, you know, or even just another  
9 group like RTI or somebody just to make sure that the  
10 questions --

11 DR. DREYLING: At this point, we've had the  
12 Subcommittee look at. We're having NACMCF review it.  
13 We are having peer reviews done, and they have been  
14 given the prompts and these are food safety experts,  
15 some of them will be. But if you feel that we need  
16 to have further outside review, you may want to make  
17 that suggestion.

18 DR. RYBOLT: The peer review is going on  
19 right now?

20 DR. DREYLING: Peer review is underway.

21 DR. RYBOLT: And you're seeking input from  
22 this Committee as well?

1 DR. DREYLING: Right.

2 MR. ELFERING: And who is doing the peer  
3 review on this? You said food safety experts.

4 DR. DREYLING: We have a group that has  
5 representatives from public health, from food  
6 microbiology and food technology, from biostatistics  
7 because we have given them the entire report to peer  
8 review and we have seven peer reviewers.

9 MR. ELFERING: All within FSIS?

10 DR. DREYLING: No, these are all external  
11 academics I believe that are reviewing it. We don't  
12 know --

13 DR. MACZKA: We don't know who they are.  
14 We told them --

15 DR. DREYLING: Carol, talk here.

16 DR. MACZKA: We don't know the names of the  
17 individuals that are reviewing this but we told the  
18 contractor what the types of expertise as we need to  
19 have represented for review. So there are food  
20 safety experts. They are people with statistical,  
21 you know, expertise and we gave them a long list of  
22 expertises needed.

1 DR. RYBOLT: And that's specifically for  
2 the prompts, too? I mean I know that's going on for  
3 the risk assessment and everything else but the  
4 prompts as well?

5 DR. MACZKA: They were given the entire  
6 processing and slaughter report. So the risk  
7 assessment is in there, all the prompts are in there.  
8 They were given the whole report to review.

9 MR. SMITH: I think it's important, and  
10 Ms. Dreyling, you can tell me if I'm wrong on this,  
11 but to understand this, I mean this just wasn't  
12 created for this. This was an outgrowth of the FSIS  
13 HACCP guide. It is -- and so what I would expect  
14 that these things, these questions -- this is Bill  
15 Smith by the way, these questions would be lined up  
16 very closely with the HACCP guide. Do -- if you went  
17 to the HACCP guide for poultry slaughter or for  
18 ready-to-eat, not fully cooked, or fully cooked, not  
19 shelf stable, that you would see these line up. So  
20 we have been on record before and I think that was  
21 the starting point, and then -- am I correct on that?

22 DR. ARRINGTON: Yes.

1           MR. SMITH:   And then that's what the --  
2 that was the basis and that was reviewed and shared  
3 publicly in the past.   And then that's what's being  
4 peer reviewed, part of that.   So that's just a little  
5 history on it.   We just didn't create these for this,  
6 for the NACMPI --

7           MR. ELFERING:   One of the things -- this is  
8 Kevin Elfering.   One of the things I guess that I  
9 look at when I look at these prompts is in many  
10 instances, you would probably go back to the hazard  
11 analysis in the flow diagram of the plant.   Now for  
12 processing, it's going to be much more complex than a  
13 slaughter operation.   You're going to have multiple  
14 types of different processing, and I think one of the  
15 things -- I think that the slaughter one is probably  
16 a little bit straightforward but here you have a  
17 situation where you're looking at receiving and  
18 you're looking at processing and then looking at  
19 post-lethality, and I think that you're going to have  
20 to kind of weight those a little bit to a higher  
21 priority because to me, in doing the hazard analysis,  
22 you know, receiving is certainly going to be

1 something that you're going to be concerned with, but  
2 one of the biggest issues with receiving product is  
3 you don't know what happens to it before it got here.

4           So really does the plant really have a lot  
5 of control on receiving product? They do, doing an  
6 inspection when you're receiving product, maybe  
7 taking some temperature checks, but if you're looking  
8 at a fully cooked product, you're going to have a  
9 lethality step further down the process. So you're  
10 going to have to, you're going to have to put some  
11 type of priority on some of these prompts as well and  
12 maybe having higher weight on some of them.

13           DR. ARRINGTON: Yeah, and on the one on  
14 receiving, we were looking at that as if a plant was  
15 not -- had product in that was obviously had problems  
16 with it and they were not doing something to take  
17 care of those problems, that might be an indication  
18 that they also were not doing very good control at  
19 other points.

20           So it wants the prompt to really look at  
21 the post-lethality more than the receiving in and of  
22 itself tells you about post-lethality. So I

1 understand what you're saying, and I also -- doing  
2 the priorities of the prompts might be a good way to  
3 get at that. That's just one thing. It just  
4 happened to be the first thing we wrote because of  
5 the process flow. It did not mean that it was  
6 necessarily the most important thing that you might  
7 be prompted to go look at the vulnerable points.

8 MR. ELFERING: Any other comments from the  
9 Committee members? Stan.

10 DR. STROMBERG: This is Stan Stromberg. I  
11 kind of go along with what Kevin was talking about.  
12 I also kind of questioned prompt 5, number 1, I  
13 wonder how likely if something like that would happen  
14 where an establishment's going to use an unvalidated  
15 cooling model to determine product disposition, and  
16 then I also wonder is an in-plant inspector going to  
17 be expected to recognize this or is it something more  
18 than an EIAO could do. So I really wonder how  
19 important this prompt is as far as on -- I just -- in  
20 my experience, I've not ever heard of someone not  
21 using a validated cooling model to determine product  
22 disposition. I'm assuming it could happen, but I'm

1 wondering, is it something that is really likely to  
2 happen or not?

3 DR. ARRINGTON: We've gotten these  
4 questions before out in Omaha. So it does occur  
5 where you wouldn't think it would but it does occur.

6 MR. SMITH: And this -- and I perfectly  
7 agree with Isabel. Where these comes into play, and  
8 it does happen a lot, is if you have a cooling  
9 process and then you have a cooling deviation. In  
10 the eighties, there was roast beef deviations and  
11 then ever since, you know, the Agency had a cool down  
12 Appendix A, and so those are the validated processes.

13 However, when there's a deviation and  
14 plants find that they deviate from that, then they  
15 try sometimes to apply the ARS model and they, you  
16 know, they do pure math and they don't know all the  
17 conditions that are in the model, and that's where it  
18 becomes unvalidated. So it's usually in a deviation  
19 scenario where that would occur, and I agree, but  
20 that's how that would come about and that's where it  
21 becomes relevant.

22 I think I agree with Kevin and you that

1 what's key here is the HACCP plan, and it is the flow  
2 chart, and it is the hazard analysis. So these are  
3 what, you know, to guide thinking, but what's always  
4 going to be the controlling factor will be the hazard  
5 analysis, the flow chart and that will be in the  
6 profile that then they can refer back to, and that  
7 would be where the prompts would take them for that  
8 particular operation.

9 MR. ELFERING: And, Mark, did you have a  
10 question as well?

11 MR. SCHAD: Yeah, I just had a comment, and  
12 I'm not sure this is anything new because that's what  
13 I was thinking about, prioritizing, and really from  
14 the plant standpoint, I mean you see a problem,  
15 deviation, whatever it might be, you might mentally  
16 or write down on a piece of paper, you know, what are  
17 the possible causes, what are the possible things  
18 that could be a result of this deviation, and what  
19 the most likely problem -- the most likely negative  
20 result and you look down in your priorities. So I'm  
21 not saying that they do, but I'm saying I'm really in  
22 agreement with you.

1           MR. ELFERING: And I think another thing to  
2 consider is just because of the complexity of  
3 processing, especially in a plant that's doing heat  
4 processing, is you can have prompts I guess but  
5 because the processes are so different and especially  
6 in post-lethality handling, you know, you've got some  
7 really complex processes out there that are using  
8 high pressure after packing to, to eliminate  
9 microorganisms, further heat process, and so I think  
10 that you really -- I don't know if you -- this is not  
11 such an easy one to put a very simple model to it.  
12 So why did you have to give us such a difficult one  
13 to talk about. But I think it is just very complex,  
14 and I don't know if you can have just a simple plan  
15 so to speak.

16           DR. MACZKA: One of the things we did, we  
17 took the 9 HACCP categories and based upon the expert  
18 elicitation, which looked at 25 product categories,  
19 those 25 product categories were collapsed into the 9  
20 HACCP categories. And then in each of those things,  
21 we developed one of these flow diagrams which  
22 identify vulnerable points. And, yes, the processes

1 may differ from plant to plant, but we felt there are  
2 certain common steps, you know, within each of these  
3 25 or the 9 that we can identify that are common  
4 between all establishments and then with that, to  
5 identify for a particular HACCP category, what the  
6 vulnerable points are. So we think that there are  
7 some commonalities there that can be compared, and  
8 it's important to be able to compare, so you can  
9 compare establishment to establishment. So you have  
10 to look at some commonalities between them.

11 MR. ELFERING: What pathogens are you  
12 targeting for fully cooked, *Listeria monocytogenes*,  
13 *Salmonella* --

14 MR. SCHAD: *Clostridium perfringens* is a  
15 concern as well.

16 MR. ELFERING: -- *clostridium perfringens*.  
17 Are you considering -- what are -- what pathogens are  
18 you actually considering?

19 DR. ARRINGTON: I think *Lm*, *Salmonella*,  
20 O157, would that be beef products? Heat treated, not  
21 shelf stable.

22 MR. SCHAD: This is Mark Schad. When they

1 take a sample for -- a finished sample, they're  
2 analyzing at least in my establishment, for *Lm* and  
3 *Salmonella*.

4 MS. TUCKER-FOREMAN: This is Carol. I'm  
5 having trouble hearing the voices in the background.

6 MR. ELFERING: Okay. We'll try to make  
7 sure that we talk right into the microphones.

8 MS. TUCKER-FOREMAN: Thank you.

9 MR. ELFERING: I know my voice carries  
10 pretty well, but not everybody's always does. You  
11 can probably hear me without the telephone, Carol.

12 MS. TUCKER-FOREMAN: I also, I have a  
13 concern here about prompt descriptions. It says that  
14 it's -- for the *Salmonella* performance standard,  
15 *Salmonella* performance standard is only an  
16 industrywide average. It is not a public health  
17 standard as -- acknowledged this morning and there  
18 isn't a standard for *Campylobacter*. So I don't know  
19 how these relate to public health. I particularly  
20 don't know how the *Salmonella* standard that was --  
21 solely based on an industry average can tell you that  
22 these are the important things to do in a public

1 health problem.

2 MR. ELFERING: Carol, is that -- that must  
3 -- is that in the poultry slaughter?

4 MS. TUCKER-FOREMAN: I'm looking at  
5 Appendix B, prompt 1, establishment exceeds half the  
6 standard for *Salmonella* or exceeds the standard for  
7 *Campylobacter* and generic *E. coli*. Am I someplace  
8 wrong?

9 MR. ELFERING: That's on the poultry  
10 slaughter.

11 MS. TUCKER-FOREMAN: That's right.

12 MR. ELFERING: We're trying to deal with  
13 the fully cooked, not shelf stable one first I think,  
14 and then we'll switch over to the poultry slaughter  
15 one and try to take them one at a time.

16 MS. TUCKER-FOREMAN: I think that's what I  
17 missed when I said I couldn't hear.

18 MR. ELFERING: I'm sorry. That's -- and I  
19 don't know if you have -- it's in the other Appendix  
20 B, on -- it starts on page 47.

21 MS. TUCKER-FOREMAN: Well, I'll find it.  
22 On that prompt, don't slow down for me. Go ahead.

1           MR. ELFERING: No, I was just going to get  
2 it for you though. It's called Appendix B, Public  
3 Health Risk-Based Inspection System, Focused  
4 Inspection Prompts and Questions. And it's -- it  
5 looks like it's --

6           DR. CUTTER: Kevin, this is Cathy from Penn  
7 State. We're looking at B-47. Is that where you  
8 guys are?

9           MR. ELFERING: Yes. It's a 75-page  
10 document, and we're starting at B-47.

11          DR. CUTTER: Okay. Thanks.

12          MR. ELFERING: So, Cathy, I didn't know you  
13 were on the line.

14          DR. CUTTER: Yeah, I'm kind of lurking in  
15 the background.

16          COURT REPORTER: Could you have her  
17 identify herself?

18          MR. ELFERING: Yes. Catherine, could you  
19 identify yourself please?

20          DR. CUTTER: Catherine Cutter, Penn State  
21 University.

22          MR. ELFERING: Thanks.

1 MS. TUCKER-FOREMAN: I have the -- pages of  
2 B in this book and I have to see if that actually --  
3 pages twice. You all go ahead, and I'll try to find  
4 it and come back to you.

5 MR. ELFERING: That one we didn't hear,  
6 Carol.

7 MS. TUCKER-FOREMAN: I said that I have  
8 copies of the first several pages of Appendix B  
9 rather than a complete Appendix B that FSIS sent me.  
10 I think I probably have a complete copy in other  
11 papers. So you all go ahead and talk, and I will  
12 look for the rest of Appendix B.

13 MR. ELFERING: Okay.

14 MR. SCHAD: Kevin?

15 MR. ELFERING: Yes.

16 MR. SCHAD: I'd just like to make -- this  
17 is Mark Schad. I'd like to make a comment just on  
18 the vulnerable points, and I think it's going to be  
19 getting a little of confusion on the CCP and the CP  
20 in there, but in this category, fully cooked, not  
21 shelf stable, at least I think maybe you can  
22 prioritize the vulnerable points, too. For example,

1 as far as pre-operational, looking at the equipment  
2 in a fully cooked, not shelf stable operation would  
3 be more critical than a pre-operational in the cooked  
4 area, than it would be in the raw meat area.

5 MR. ELFERING: Yes, I think that is  
6 actually a very important sanitation out in the --  
7 and most of these plants do have I would assume or at  
8 least thought that most of them have set up where  
9 they have a raw product area and a cooked product,  
10 and the sanitation in the cooked product area  
11 certainly should be a higher priority than the raw  
12 product side.

13 DR. MACZKA: You're basing that on -- I  
14 mean basically I justified the vulnerable points  
15 based upon the literature that showed that if you  
16 didn't control at this particular point, you know,  
17 there could be the greatest microbial, you know,  
18 introduction or growth. So we used the literature to  
19 just the vulnerable points. We did not prioritize  
20 them, that is true but to do such a prioritization, I  
21 would think we need something solid to hang our hat  
22 on.

1           MR. ELFERING: Well, I think one of the  
2 things that -- you're thinking that you might have a  
3 high microbiological log in the raw product, and I  
4 think, you know, there again you're going to have to  
5 look at the lethality process but most of these  
6 facilities are probably getting a six log reduction.  
7 If you're coming into your plant with raw ingredients  
8 or having microorganisms at that level, because of  
9 sanitation, you've got more problems going on than  
10 food safety, and I just think that from the  
11 standpoint of food safety, it is much more critical  
12 to have -- to be concentrating more on the sanitation  
13 side of the cooked product rather than the raw  
14 product. But I don't know. Would anybody disagree  
15 with that? Feel free. Post-lethality, you know, in  
16 the packaging area is probably even -- is going to be  
17 even more critical.

18           Any other comments on that?

19           DR. MACZKA: What Bill was whispering to me  
20 before is that instead of maybe being hung up on the  
21 specifics of this particular HACCP procedure, that  
22 maybe what we need is some ideas from you as to

1 should we be using the HACCP guide, you know,  
2 something more, in order to identify these prompts or  
3 vulnerable points. What ways would you suggest to us  
4 to identify these? Maybe at a higher level instead  
5 of being down at this level. Is the HACCP guide a  
6 good idea to use.

7 MR. SMITH: Yeah, I'm piggy-backing. You  
8 know, you've already made statements about key  
9 components being here pre-operational, delivery of  
10 lethality, prevention of outgrowth of spore formers,  
11 and then that all gets into that sanitation is more  
12 important in post-lethality because, you know,  
13 there's obviously the -- is being destroyed and you  
14 don't want the spore formers going out. So that's  
15 why it becomes more important in that than the other.  
16 And so I guess some agreement, these are key  
17 categories or are these the right major categories  
18 and then, you know, as you all just said, I think you  
19 made one strong recommendation already, which  
20 involves the flow chart in the HACCP plan, and so I  
21 think that's -- instead of, you know, receiving is  
22 important in a RTE if, in fact, they're using rework

1 -- I mean, if they're returned product, that's where  
2 it becomes critical, I agree with you. Otherwise,  
3 and then there are some plants that just buy  
4 distressed returned ready-to-eat and so then  
5 receiving would be very critical but again that gets  
6 back to your point about the hazard analysis and flow  
7 charts should drive a lot -- I think they have, you  
8 know, they've done a great job hitting the major  
9 categories in the literature if you'd stand that up.  
10 So --

11 MS. TUCKER-FOREMAN: Kevin?

12 MR. SMITH: -- classifying and categorizing  
13 which maybe you can get some advice that way.

14 MS. TUCKER-FOREMAN: Hello?

15 MR. SMITH: I don't know. I don't want  
16 to --

17 MS. TUCKER FOREMAN: Hello.

18 MR. ELFERING: Yes, Carol.

19 MS. TUCKER-FOREMAN: I'm just getting --  
20 the person who was just speaking, I got about every  
21 third word and then somebody, and I don't even know  
22 who it is but --

1 COURT REPORTER: I'm having trouble  
2 hearing. You need to be on mic --

3 MR. ELFERING: Yeah, we'll have to make  
4 sure that everybody is getting a little closer to the  
5 microphones here, Carol.

6 MS. TUCKER-FOREMAN: Thank you. I do have  
7 the material now.

8 MR. ELFERING: Okay. Edna, do you have a  
9 comment or question?

10 DR. NEGRON-BRAVO: Yes. B-48, the second  
11 from -- there are some questions that are not really  
12 clear how they relate to the -- description like pre-  
13 operational equipment cleaning and then the  
14 vulnerable points comes. It's not a CCP, those  
15 plants, the post-lethality, how would that question  
16 be tied to the operational equipment cleaning? So --  
17 and the second one is rework and carryover -- in the  
18 hazard analysis, how would that be -- because I think  
19 that these are questions that you want them to look  
20 and think over when they find that?

21 MR. SMITH: This is Bill Smith, and again  
22 Ilene or Isabel may be in a much better position to

1 describe but maybe we haven't done a good job on how  
2 we get to this point. And so an inspector gets their  
3 schedule to do pre-operational sanitation. In doing  
4 that, they find a problem with the equipment  
5 cleaning. Some combination of, I don't think it's 1,  
6 but let's say over a 2 week period, in a 2 week  
7 period, that they get 4 of these. That would then  
8 trigger within the system to go look at all these  
9 points and so it's not just because pre-op drove it.  
10 It's because you have -- you're not demonstrating  
11 control of pre-op. Then all of a sudden, the entire  
12 RTE process. The question you want answered is are  
13 they controlling the process and then they go through  
14 each and every one of these from start to finish,  
15 correct, receiving this, in order to make a  
16 determination is the plant maintaining process  
17 control? That's really what you want. If you see a  
18 loss of process control somewhere along the line,  
19 then you want to go back and look at how are they  
20 delivering it all along the line for this product  
21 type. That's -- is that fair, the categorization  
22 what we're doing?

1           MR. ELFERING: And I think again, you know,  
2 it's certainly more clear in the poultry slaughter  
3 scenario where you have, you know, are doing --  
4 you're finding that you have birds that have adhering  
5 fecal material going into the chiller. With  
6 processing, it's just not as easy, and I think that,  
7 you know, again the plant has done a hazard analysis.  
8 You have a flow diagram. I would almost think you  
9 would have to look at the HACCP plan because in some  
10 cases, you're going to have a processing plant that  
11 is going to have receiving as a CCP. So then all of  
12 a sudden, a CCP at receiving becomes a whole lot more  
13 important that they're meeting the critical limits of  
14 the critical control point, than if it's just a CP,  
15 just a control point.

16           So I almost think that you have to be  
17 looking at -- with processing, you almost have to be  
18 doing it hand in hand with their HACCP plan.

19           DR. ARNOLD: And, in essence -- this is  
20 Ilene Arnold. In essence, that is what we're doing.  
21 If you remember what Charlie Gioglio presented in the  
22 domestic inspection model, there's going to be

1 profile information that is a lot more in depth than  
2 we currently have, and that profile information is  
3 actually going to drive our vulnerable points and our  
4 prompts. So, if we have in the profile that they  
5 have a CCP at receiving, that will not come up as one  
6 of the prompts because it's already being verified  
7 under the normal HACCP procedures as a CCP.

8           This is not intended to look at the CCPs.  
9 This is intended to look at those other points that  
10 are addressed in the hazard analysis where the  
11 determination has been made that there is not a  
12 hazard reasonably likely to occur, we have another  
13 control program in place to look at those control  
14 programs as well because we're moving towards the  
15 next step where there is more of a systems approach  
16 to looking at this.

17           The inspector -- some of them are doing it  
18 right now. Some of them are not. Like I said in my  
19 presentation, we need to connect all the dots. It's  
20 just not a matter of looking at a hazard analysis and  
21 just going out and doing verification at a CCP  
22 because there is other things going on. So the way

1 we've designed the system is they're all going to  
2 talk together. So we have this module over here  
3 where we have the domestic inspection module where  
4 it's actually driving the inspector in their regular  
5 procedures and then we have this other part that is  
6 going to be prompts associated with information  
7 gathered from that system.

8 So, if you look at it, there's parts, and  
9 then you have the whole Public Health Information  
10 System that's feeding into the actual Public Health  
11 Risk-Based Inspection System.

12 MR. ELFERING: And I think that is just  
13 some of my misunderstanding. I was not aware that  
14 CCPs were -- each individual plants, CCPs are going  
15 to be put into this plant profile.

16 DR. ARNOLD: Yes. Yes, it is.

17 MR. ELFERING: So there again, then it  
18 becomes more difficult to try to come up with some  
19 generic areas for prompts because each plant is going  
20 to be different. You've identified the prompts. I  
21 mean you certainly have done that. I mean you're  
22 looking at all parts of a plant, receiving,

1 processing and post-lethality, and I think you've  
2 included them all, but it's just going to be -- each  
3 individual plant is going to be very complex, and  
4 it's going to be different. You're not going to have  
5 too many plants that are the same.

6 DR. ARRINGTON: This is Isabel Arrington.  
7 Are there prompts in this particular -- or are there  
8 the vulnerable points in this, are all of those  
9 vulnerable in your opinion? What I mean is we've  
10 looked at it from the standpoint of the literature  
11 and we were coming up with all those points are. I  
12 guess that would be something that I would like  
13 feedback on.

14 MR. ELFERING: Well, I guess, I'm only  
15 looking at my experience in investigating foodborne  
16 illness outbreaks, and there's vulnerabilities in  
17 just about any part of the food system. I mean, if  
18 you look at it from a systems approach, it's only as  
19 strong as the weakest link. So you are going to have  
20 vulnerabilities. I think there are some things  
21 though that you certainly can prioritize, that are  
22 going to be more areas that are going to be more

1 vulnerable in a plant. And I think if you're going  
2 to be looking at trying to do anything like that,  
3 that would certainly be of value to do this  
4 prioritization.

5 DR. ARRINGTON: I see what you're saying.

6 MR. ELFERING: Well, I mean, if you look at  
7 the food system and you look at the outbreaks that  
8 we've had over the years, there's always some anomaly  
9 that happens and sometimes you can usually -- it's  
10 pretty simple on how contamination occurred, but  
11 there's a lot of foodborne illness outbreaks. I mean  
12 who would have ever thought that we would have a  
13 recall on foodborne illness outbreaks due to  
14 pepperoni pizza. I mean, you know, these are just  
15 things that are very difficult to predict.

16 Going back to problems with *Salmonella* and  
17 ice cream. I mean, they're just very difficult to  
18 try to figure out what is the vulnerable points in  
19 any process. They're all vulnerable.

20 MR. SCHAD: This is Mark Schad. If I can  
21 make a comment on that. When I first looked at these  
22 vulnerable points, the question that came in my mind,

1 or the thought that came in my mind, it looks like  
2 FSIS listed everything, and you can't deny -- like  
3 Kevin said, you can't deny that any of these are not  
4 important but some of these are much more, you know,  
5 likely -- I don't want into the HACCP -- too much,  
6 but more likely to occur than other ones that are  
7 very remote. So, you know, you need to prioritize  
8 your resources on that.

9 DR. ARRINGTON: All right. And I wanted to  
10 compare them to the poultry slaughter, when we get to  
11 it, where we did say that certain steps were perhaps  
12 more vulnerable. So that's why I was asking if you  
13 saw in that model in that particular one, if there  
14 were any. I think what you're saying is that all of  
15 them are.

16 MR. ELFERING: And I think especially in  
17 processing, you know. You always have to look at the  
18 ultimate end product, and to me there's a huge  
19 difference between a product that's going out of a  
20 facility that's raw and a product that's going out of  
21 a facility that's been fully cooked and ready to eat.  
22 You know, if you really look at the pure HACCP

1 system, can you really have a HACCP system with a  
2 product that is not ready to eat. I don't believe  
3 you can. You can have the principles of HACCP, but  
4 you really don't have true HACCP unless that product  
5 has received some type of an intervention that is  
6 either a kill step, reduced to an acceptable level or  
7 eliminated, and you can't assure that at all with a  
8 raw product, just by virtue of the numbers of  
9 *Salmonella* and *Campylobacter* in poultry. It's still  
10 considered a safe product even though you have levels  
11 of organisms there that are pathogens. A fully  
12 cooked, ready-to-eat product you don't have -- you  
13 have much higher standards.

14           So, I would say that in a process like  
15 that, you're vulnerable steps are going to be more --  
16 I would say that you would have more vulnerable steps  
17 in a product that's ready to eat rather than you do  
18 for reducing levels. Reducing levels are bringing  
19 the numbers down. So, if you can bring the numbers  
20 of *Campylobacter* from 80 percent down to 50 percent,  
21 you're certainly making some advances towards food  
22 safety, but it's a much different standard than a

1 ready-to-eat product, than a fully cooked product.

2           So do we want to discuss the poultry  
3 processing one at all or --

4           DR. ARRINGTON: Yes, and then if we need  
5 to, we can go back. We were just talking here about  
6 which of the steps were covered. So we can do that,  
7 but that's what I would like to do if everybody else  
8 would, would be to go into the poultry --

9           DR. MACZKA: And also can you just think a  
10 little bit about the definition that we use to define  
11 vulnerable points. We say -- this is how we defined  
12 it and see if you are in agreement with it. Where  
13 greatest microbial contamination or growth occurs if  
14 process control is not maintained. That's how we  
15 defined it. Is that a good way to define it and with  
16 that definition, I mean, I guess I'm having a hard  
17 time to think that every -- that, yes, there is  
18 vulnerability throughout but there has to be some  
19 places that we really want to concentrate your  
20 activities more so than other places, even I would  
21 think in processing.

22           MR. ELFERING: And I think that's one of

1 the points that a number of people have been trying  
2 to get across is that there are different areas in a  
3 plant where you should be prioritizing. You can't  
4 just look at sanitation and say sanitation is, is a  
5 vulnerable point. You have vulnerable -- you have a  
6 different vulnerable point in packaging in a fully  
7 cooked, ready-to-eat product. You do at post-  
8 lethality if you're doing any storage. It's much  
9 different than the raw side. So, you know, you're --

10 DR. MACZKA: Carol. So you're saying to  
11 prioritize these points.

12 MR. ELFERING: Yes.

13 DR. MACZKA: You're in agreement.

14 MR. ELFERING: I think, I think that they  
15 definitely have to be. And again, to utilize your  
16 resources. If you have a fully cooked, ready-to-eat  
17 product and you're having, you're having positive  
18 results, the first place that I would be going to is,  
19 is looking at the sanitation in post-lethality areas,  
20 either storage or processing. I certainly wouldn't  
21 -- the first place I wouldn't be going to would be on  
22 the raw product side to see what the sanitation is.

1 Check the lethality first. That would be number one.

2 DR. NEGRON-BRAVO: Edna. I'm just trying  
3 to understand a little bit better and maybe  
4 concentrating my thinking, but when we were talking  
5 about vulnerable points, we are trying to relate that  
6 to maybe things that had happened and when we look  
7 back to this outbreak it was caused maybe because  
8 there's many other things that were not really hazard  
9 or control points, where the experience has been that  
10 we do not detect those vulnerable points were not in  
11 control maybe in that cases, and we are going to  
12 identify that so that for the future, we might not  
13 necessarily be only looking to CCP but to trigger  
14 some action or control points, that we are calling  
15 now vulnerable points. And it is correct that we  
16 have vulnerable all across the line for now. The  
17 information that the Agency has due to the NRS that  
18 they have collected may be related to something,  
19 might guide us to some points that we'll have to  
20 strength along the chain. So that's the importance  
21 of this kind of narrowing down.

22 Now we need to know maybe some of these

1 questions are not necessarily appropriate for that  
2 plant. Maybe right now I might not be able to  
3 address all of them but after this discussion, maybe  
4 we will be able to comment more about these questions  
5 because the time to go over all these questions and  
6 the appropriate question or the prompt might be not  
7 necessarily all of them that good at this point. But  
8 we are working on it.

9 MR. ELFERING: And I think one of the  
10 things that Bill had said was that there's going to  
11 be kind of a little bit of a test run with some of  
12 these, and I think that's one of the things -- I  
13 think that will be one of our recommendations is that  
14 these are put into some type of a trial, and you're  
15 going to be able to determine, I would think, that  
16 some of them are going to be more useful than others.

17 MS. JONES: Cheryl Jones. I just wanted to  
18 follow up. Having actually designed systems,  
19 listening -- to me this is a very high level design  
20 of an existing system, and you said, some of these  
21 prompts, because of the differences in all the  
22 plants, all these prompts aren't going to apply.

1           I think one of the major recommendations  
2 would have to be that this has to actually be tested  
3 by people in the field at actually a number of  
4 different plants, to see -- to actually identify the  
5 flexibility that you have to build into the system  
6 that you're designing. Otherwise, I've designed  
7 purchasing systems -- I had to design a purchasing  
8 system that I had to make fit a need as opposed to  
9 building the system around the need. And so what  
10 happens is if you get too much information on the  
11 actual prompt, you might find that some of this is  
12 relevant, some of it's not, and you can't change it.

13           So I think one of the -- before you can  
14 finish, and say this is like a bottom line -- these  
15 are all the prompts that would be in place, you have  
16 to actually identify how much flexibility you have to  
17 build into this system to say, okay, we need a  
18 minimum of 12 prompts at this plant, and we need a  
19 maximum of -- I mean a maximum of 12 plants with a  
20 prompt in one area, a minimum of 3. So you have to  
21 build in 12 prompt capability and the ability to make  
22 those identify a particular prompt but then what you

1 also have to realize is that the more prompts you  
2 have, the more flexibility you have, the more  
3 complicated it is to actually set the particular  
4 profile for each individual plant because you have to  
5 go in, you started with the generic profile, but then  
6 you have to build on whatever the areas are, and that  
7 makes it more complicated, makes it more resource  
8 intensive to actually roll out the actual system or  
9 design. I just wanted to make that comment.

10 MR. ELFERING: Very good. I think that  
11 that's what one of our recommendations would be, that  
12 this does go through, and you may even want to do a  
13 trial run before it even goes to a plant. I mean  
14 come up with some scenarios like you already have and  
15 be inventive and, you know, really come up with some  
16 true situations that have occurred and see how you  
17 can work through it before it even goes to the field.  
18 Catherine --

19 MR. SMITH: I just wanted to -- this is  
20 Bill Smith, and I think everybody here agrees and, in  
21 fact, they're doing that now. I believe the poultry  
22 was tested. I mean there was a dry run on some of

1 that.

2 DR. DREYLING: They did visit -- for the  
3 design of the Public Health Information System, the  
4 team that's working on establishing the profile did  
5 visit both HIMP and non-HIMP poultry establishments  
6 and they practice putting the information into the  
7 profile to see how easy it would be to access that  
8 information and to see that it would be able to be  
9 completed. So they are doing that, and they do plant  
10 to do more field testing with this entire system, and  
11 we certainly will be testing the prompts. It's  
12 absolutely necessarily. That was a very good point,  
13 Cheryl.

14 DR. RYBOLT: This kind of follows up --  
15 this is Michael Rybolt by the way. This is a follow  
16 up to what Dr. Harris had asked with Isabel -- sorry  
17 -- earlier but, you know, as a possibility or  
18 recommendation from the Committee, as part of the  
19 testing, you know, you may have already done some but  
20 further test it is get some inspectors together and  
21 go through some of this to see what their responses  
22 will be to the questions, kind of a correlation if

1 you will.

2 DR. MACZKA: And one of the things Bill  
3 mentioned when he was doing his presentation is that  
4 there will be user testing of these -- of the system  
5 and of these questions.

6 DR. RYBOLT: And refinement if needed, et  
7 cetera.

8 DR. NEGRON-BRAVO: Edna. For example, in  
9 those experiences that we have had, once we can have  
10 -- and say would that have been prevented, could that  
11 have been prevented if we had this in place? Would  
12 that -- this system that we are proposing, would that  
13 prevent, have prevented that outbreak? So you could  
14 see whatever you are setting up will maybe work.

15 DR. MACZKA: that was the idea behind --  
16 this is Carol -- presenting these case studies. It  
17 was, okay, here's the system as we propose it. Would  
18 it have helped identify those problems and prevented  
19 them early on and that's why we did present those  
20 case studies. We didn't look at others but we did  
21 look -- provide you two examples at this meeting.

22 DR. YANCY: Kevin, Al Yancy, U.S. Poultry

1 and Egg Association. If I might, I think that gives  
2 me the opportunity to say one of the things that we  
3 were interested in saying if such an opportunity  
4 presented itself. And I think that the Topps case  
5 that was presented yesterday and the poultry case  
6 study that Dr. Arrington presented today show that  
7 there was a system breakdown on both sides, that  
8 obviously the industry wasn't doing what it needed to  
9 do and the Agency was missing fatal cues that the  
10 industry was throwing out, and so it begs the  
11 question and it's certainly one that I think is  
12 answerable, and that is wasn't that really a resource  
13 issue. In my opinion, by that I mean, yes, it was  
14 and that could simply -- the properly educated  
15 employees in positions to make the decisions  
16 necessary with regard to the data that was coming in,  
17 to oversee that data that was coming in and make  
18 those decisions, or was it a time factor or was it a  
19 management tool that was missing to be able to handle  
20 this huge amount of data that was coming in and route  
21 the critical information to the parties that needed  
22 it or was it some combination thereof.

1           And, I think the way the Agency is  
2 proposing this program, it seems to indicate to us,  
3 to the U.S. Poultry and Egg, to me, Dr. Yancy, that  
4 the tool is the issue. It's not so much the other  
5 factors, the time and the education, especially when  
6 the proposal is speaking about neutrality of resource  
7 which I don't see because we're talking about, I  
8 think Dr. Arrington mentioned today, setting aside  
9 other tasks that might need to be set aside to allow  
10 for these additional directed tasks that may be  
11 resulting from results. So that to me sounds like  
12 resource allocation, and by that I mean looking  
13 generally at employees as a resource and not just  
14 employees, but educated resources and I don't mean  
15 they're ignorant. I mean having the proper education  
16 and the proper authority to make the decisions  
17 necessary.

18           It's also a management tool. It's also  
19 time, and so if the Agency's done the hard work and  
20 decided that the only thing that's really necessary  
21 regarding resource allocation is this management  
22 tool, then I think that we certainly support

1 education and the industry and USDA looking more  
2 deeply at these processes to make sure that the  
3 thought processes put behind the development of these  
4 programs is accurate. But if the whole idea is that  
5 we haven't looked at, and by we, I mean the Agency,  
6 the other aspects, the management tool, the  
7 education, then asking these questions is going to do  
8 exactly what some of us, some of the Committee folks  
9 have said they're concerned about, and that it  
10 basically asking, ask no questions and for lack of a  
11 better term, potentially dumbing down this thought  
12 process and spoon feeding the information to them so  
13 that they can shoot it into a system that will get it  
14 up to somebody that can make that decision.

15           And I thought we had talked about before,  
16 that risk-based inspection, the previous incarnation,  
17 was going to be allocating resources where they were  
18 most effective, and that was shifting it from one  
19 place to another and that's not what we're talking  
20 about so much now. We're talking about neutrality of  
21 resource and I hope that we're making the right  
22 decision.

1           MR. SMITH: This is Bill Smith, FSIS. I  
2 agree with much of what you said there. A couple of  
3 things. We're asking your comment on this component,  
4 fully agree education, training, management control  
5 system is part of that and I think we laid out how,  
6 you know, that was one of the four -- those were the  
7 four principles that you just went through which were  
8 in the OIG Report, and we addressed how we're going  
9 to do each and every one of them.

10           So this is one component, and I agree it's  
11 not in isolation, so that we need a management  
12 control system.

13           This, this system here was to again -- I'm  
14 not sure we've explained fully how we want this to  
15 work in that the inspector does their normal HACCP or  
16 sanitation procedure among their other full  
17 complement of inspection procedures.

18           At some point, a trigger to look more  
19 closely, and then at that point, you're right, it is  
20 a change in what the inspector does, and so instead  
21 of an inspector being scheduled on let's say a HACCP  
22 O3G here, and an O3G2, which they do today instead of

1 looking at this, this and this, they will be asked to  
2 look at these areas. And so I'm not sure that's a  
3 significant time that that has to be tested is what  
4 you're telling us.

5           So we're just focusing what they do as  
6 opposed to saying, you know, on this specific lot,  
7 you look at how this went through. You want to see  
8 how the process controls in addition to CCPs were  
9 delivered. So it is a resource -- it is telling them  
10 to do something different. Hopefully it's not a big  
11 time -- significant difference if they're, you know,  
12 it's just a reallocation of focus.

13           And then furthermore, nobody's -- if, in  
14 fact, we get into this and it becomes important  
15 especially in Level 2, where you are being directed  
16 to do these, then, yeah, the Agency knows it has to  
17 give up maybe less, less processing defects in a  
18 poultry operation, less trim or the line checks,  
19 finished product stand checks, you know. We spend  
20 more time looking at the food safety issue and less  
21 for feathers and those kinds of things. We might  
22 even have to make decisions about labeling checks or

1 things of that nature, that if we're doing food  
2 defense even on an every day basis, maybe we do it  
3 four days a week. Those are the kinds of changes  
4 that we're talking about in order to accomplish this.

5 MR. ELFERING: Carol and Catherine, do you  
6 have any questions or comments? I want to make sure  
7 I keep you involved in this.

8 DR. CUTTER: This is Cathy. I would agree  
9 with a lot of the comments that have been made so far  
10 with regard to some of the recommendations.

11 MS. TUCKER-FOREMAN: This is Carol. I  
12 don't have any comments right now.

13 MR. ELFERING: Okay. Thanks. Tony.

14 MR. CORBO: Yeah, Tony Corbo, Food and  
15 Water Watch. Bill, you know, not too long ago you  
16 all went through an exercise of a method of assigning  
17 work that caused all sorts of heartburn. Are you  
18 envisioning having to go through that again with the  
19 implementation of this new program?

20 MR. SMITH: That is something -- I think we  
21 have to get through our user test. I think our  
22 present allocation of resources that were under that

1 system will be more than adequate to start up with  
2 here and then you would have to make decision change.  
3 Remember, there's two things there. There was a work  
4 measurement piece and then there was a classification  
5 piece, and I don't see right now -- I think the work  
6 has to be defined, tested and then you measure,  
7 measure that and you measure the classification  
8 aspects of it, but for right now, I'm not seeing -- I  
9 mean personally, I'm not seeing any major swings here  
10 I mean that any major reordering of assignments of  
11 that thing right now.

12 MR. ELFERING: If we could, why don't we  
13 discuss a little bit about the poultry slaughter  
14 prompts as well. You have, I believe, three  
15 identified as scalding, evisceration and chilling.  
16 Is that correct?

17 DR. ARRINGTON: Yes, we did, but what we  
18 have in the, in the notebooks are all the steps that  
19 are the major steps in a poultry slaughter  
20 establishment.

21 MR. ELFERING: Is there any discussion at  
22 all from the Committee on whether or not there would

1 be any other prompts that would be --

2 DR. ARRINGTON: Right, and we went through  
3 it and we're seeing that the most vulnerable ones  
4 were scalding, evisceration, online reprocessing and  
5 chilling.

6 MR. ELFERING: What and, you know, I guess  
7 again I look at, I look at things from more of a  
8 systems approach. What authority does FSIS have on  
9 farm?

10 DR. ARRINGTON: On what?

11 MR. ELFERING: Farm.

12 DR. ARRINGTON: None.

13 MR. ELFERING: None at all. How about with  
14 APHIS? Does APHIS -- in your working relationship  
15 with APHIS, do they have any authority to be on farm?

16 DR. ARRINGTON: They have some authority  
17 but I'm not sure if it relates directly to this. It  
18 relates more to the use of biologics and to animal  
19 disease.

20 MR. ELFERING: Because to be quite frank, I  
21 think that that is a vulnerability that you're kind  
22 of missing out on in not having the authority to be

1 able to -- I mean looking at again the load coming  
2 in.

3 MS. TUCKER-FOREMAN: This is Carol, and I'd  
4 like to address that because the Agency -- first of  
5 all before I go any further, I object to the prompt  
6 -- as I started to say before because it's based on  
7 something that is not shown to be public health  
8 related, is *Salmonella* performance standard which is  
9 industry average and not public health related.

10 On the receipt, when you go through the  
11 technical plan, you see very detailed -- you see some  
12 explanations of serious problems with dirty birds  
13 coming into the plant and then it -- that because the  
14 Agency's jurisdiction doesn't begin until the birds  
15 arrive for slaughter. On the other hand, the Agency  
16 could take action at slaughter to encourage companies  
17 to bring cleaner birds in. For example, if you had  
18 additional checks of the birds on arrival, you would  
19 slow the process down and if you're slowing the  
20 process down when the birds have some definable level  
21 of filth on them when they come in, people will start  
22 giving you cleaner birds I think because they don't

1 want the process slowed down.

2 MR. ELFERING: I think what would -- you  
3 broke up a little bit I think what you're trying to  
4 get at is that one of the, one of the prompts could  
5 be looking at the condition of the birds coming in,  
6 and if there's excessive amounts of fecal material,  
7 just plain dirty birds, that that would -- that could  
8 certainly be a prompt for having a slower line speed  
9 for example?

10 MS. TUCKER-FOREMAN: Yes, absolutely.

11 DR. ARRINGTON: I wanted to talk a little  
12 bit about live receiving and hanging which as you  
13 said, Kevin, we don't have on farm authority, but we  
14 do have authority at the live hang and the receiving,  
15 and one of the questions we might inquire, the  
16 inspector might inquire, is whether there are  
17 corporate programs that have some sort of control on  
18 their farm, and if they do that, and we can see those  
19 records and verify they do, then that would be a  
20 positive as far as saying they are doing things to  
21 control the process at receiving because ultimately  
22 they would be limiting the load that would come into

1 the plant.

2 Other things at live receiving would be  
3 like Carol was saying, to look at things, Carol  
4 Tucker-Foreman. You might look at the sanitation  
5 that they have on their crates, whether they are  
6 sanitizing them. That's been shown that you might  
7 have cross-contamination of microbial contamination  
8 if you don't do that, and then, of course, the  
9 sanitation -- sanitary hygiene of the employees and  
10 the traffic patterns of not having employees walking  
11 from the live hang that is a dirtier area to say the  
12 evisceration area. They're all some questions we  
13 could, we could ask that we know would influence, you  
14 know, would do something about -- talking about  
15 what's the load that's coming into this plant.

16 And I guess I'm back to when you were  
17 saying to prioritize, we did prioritize on what we  
18 presented today, and I guess that's why I'm saying  
19 back to you, we're now saying, are you, you know,  
20 what else do you want to add to that? You're saying  
21 that live receiving might be a really vulnerable  
22 point we should have as one of the more vulnerable

1 ones in the prioritization?

2 MR. ELFERING: I think by your own  
3 admission.

4 MS. TUCKER-FOREMAN: Listen, Kevin raised  
5 the point that you skipped over here and I think is  
6 particularly relevant in slaughter which is you get  
7 these prompts and they have inspectors to do, what  
8 does the inspector do when he sees that there is --  
9 when he gets prompts that they arrive and are  
10 receiving filthy crates, filthy birds, so on and so  
11 forth. Can he -- why can he not then say we're going  
12 to have to slow this down until we reach an  
13 acceptable level of bird because it clearly means  
14 that you're going to have to increase water change  
15 later down the line and do a lot of other things that  
16 accommodate the level of filth.

17 So that's really the -- on Kevin's  
18 suggestion, I think it was Kevin, about do you slow  
19 the line down then?

20 MR. ELFERING: I don't know if we're --  
21 Dr. Rybolt is here as well, and we're just discussing  
22 a little bit as to whether or not that would truly be

1 a vulnerable point because of the other hurdles  
2 afterwards with the scalding and, and all of the  
3 other interventions that are put in, and it sounded  
4 even like some plants have a pre-scald rinse,  
5 chlorinated rinse, and post-scald, pre-evisceration  
6 rinse. So I think all of those things have to be  
7 taken into consideration as well.

8 MS. TUCKER-FOREMAN: Well, then why not  
9 have a required pre-scald rinse or --

10 MR. ELFERING: And I'm not seen any, only  
11 because I don't know the poultry industry that well,  
12 but I've not seen any research that would show that  
13 live bird receiving would have an increase in the  
14 microbial load in the final product, but if there is  
15 some correlation, then maybe it would be something to  
16 be looking at.

17 MS. TUCKER-FOREMAN: I haven't seen -- the  
18 technical plan does discuss at some length the  
19 problems that you run into in a dirty flock and I  
20 noticed that under scalding, A, that the  
21 establishment had to control mechanisms to reduce the  
22 amount of dirt and organic matter other than the

1 chiller, are being implemented. What are they?  
2 That's Prompt 2.

3 MR. SMITH: Let me -- Isabel can answer  
4 that second one about Prompt 2, but again I just want  
5 to keep coming back -- this is Bill Smith, FSIS -- to  
6 how we got to the receiving room, and that is again,  
7 you know, inspectors are performing their O3J and,  
8 you know, we have a fecal failure at 10:00 and we  
9 have a fecal failure at 10:30, and that should tell  
10 us that we have -- if we have multiple fecal  
11 failures, and I'm not going to say there's any magic  
12 number, but that tells us something's -- that's  
13 raising a flag that something's wrong, and so in that  
14 scenario, what the system would do is say go back to  
15 the start now and see what's going on. So you go  
16 back to the receiving area and you see, for whatever  
17 reason, it's raining. There's mud all over the  
18 place, the birds were collected in a muddy night, and  
19 I'll use ridiculous examples. So they're coming in  
20 caked with mud. So now we know that then, you know,  
21 then the inspector -- so we know we have that  
22 condition there. So that's a flag.

1           Then the next one, if they are doing pre-  
2 scald, well, are they, you know, did that envision  
3 that would handle that scenario. If it's yes, no  
4 problem. If it's no, then is the scalding going to be  
5 able to handle it? You have an extra load, an extra  
6 problem coming in, and plants deal with this every  
7 day, and so, okay, what's being done at the scald,  
8 what's being done at the neck breaker, eviscerator,  
9 and if all those things -- if the answer to all those  
10 things is, yes, those things are being done or have  
11 been adjusted, then that's what we want to know and  
12 there's process control and that's the end of it.

13           On the other hand, if we have that scenario  
14 and, and the plants are not reacting to that, so now  
15 we know again another ridiculous example, so we have  
16 the dirty birds coming in, we have the spray wash on  
17 the neck breaker and the eviscerator is plugged up,  
18 so that's not working, and so now we're getting, you  
19 know, it's starting to build. Now you know you have  
20 -- you know you're going to have fecal material  
21 because you're controls, your barriers are not  
22 working along the way. And so at that point you

1 could come to the conclusion that you have an  
2 unsanitary condition and you may not apply the marks  
3 because you have this gross insanitation going on,  
4 building up.

5           And so that's what this system's to drive  
6 and help make -- what this is trying to do is, okay,  
7 we had an event, does that represent an insolated  
8 incident or do we have something bigger ongoing going  
9 on and if we establish there's process control, then  
10 that's good. If we establish the process controls,  
11 which include the CCPs and -- I mean the CCP in a  
12 poultry plant is only as good as the barriers that  
13 got it there. And so if they're all working, then  
14 you have confidence, you have confidence you're  
15 system's working. If they're not working, if the  
16 barriers are breaking down, then you know the  
17 efficacy or CCP now is in question and then you need  
18 to make some decisions about applying the marks. And  
19 that's really what this is trying to get to.

20           DR. ARRINGTON: And at the point where  
21 those findings were made, it would be where that  
22 inspector would probably have the IIC to weigh in and

1 also any other support they needed when they're to  
2 the point of saying whether we should apply the  
3 marks. So it's questionable about that.

4 MR. ELFERING: Well, I think one of the  
5 things and that's always when you have a system where  
6 you set up these prompts, if all of a sudden you run  
7 out of prompts and you still haven't resolved the  
8 situation, that's where you just need to rely on the  
9 person who is doing the work to do some critical  
10 thinking and you maybe had other people involved.

11 MS. TUCKER-FOREMAN: You've gone through  
12 the whole process, and the result at the end of the  
13 line is you're having your generic *E. coli* level go  
14 up, and since it's clear that FSIS is not going to be  
15 sampling for *Salmonella* and *Campylobacter* every day,  
16 how long does this problem last in the plant in the  
17 risk to human health before something is done about  
18 it and how do you delineate which birds have to go  
19 back and be reprocessed? You don't have any  
20 microbiological data real time to make a  
21 determination that this has become a public health  
22 issue.

1 DR. YANCY: Kevin, this is Al Yancy. I  
2 guess in a more veiled way, that was kind of what I  
3 was speaking to when I raised our concerns a moment  
4 ago, and that was if the purpose of this system, and  
5 I get, Dr. Smith, I get what you've intonated  
6 earlier, that this is one part of a four pronged  
7 approach to dealing with OIG recommendations and the  
8 Agency's desires.

9 But I guess my point is this. If this tool  
10 is a means by which in part by which to further the  
11 discussion between plant management, industry and  
12 USDA about the decision making that the industry has  
13 put into effect to develop and implement its  
14 programs, that's fine, to a point. But to Kevin's  
15 point and maybe he didn't mean this, and I  
16 misunderstood him, but to Kevin's point, what happens  
17 if you get to a point where the answers -- the  
18 questions don't exist. You've answered all the  
19 questions and you're still not resolved or the answer  
20 that you think should be yes is given by the plant as  
21 no because there are later things that are determined  
22 to be the real issue, are we going to find ourselves

1 at an impasse because the management isn't there, the  
2 education, the critical thinking isn't there that  
3 Kevin alluded to that needs to be there, and I agree,  
4 because all we've done is developed this program and  
5 that's it, and it's seen by some, not necessarily the  
6 folks who developed it, to be the end all be all  
7 because it's not.

8           It is a management tool. It should be a  
9 management tool, and I don't disagree with that from  
10 that perspective, but I think there's got to be a lot  
11 of care in the implementation of this, whether it's  
12 in trial or in full blown implementation and I think  
13 trial is, as you've said, the right thing to do, but  
14 I think there's got to be a lot of care in the roll  
15 out of that, the supervision of that, and the  
16 education of all those folks that are doing it  
17 because if the real problem here is a lack of  
18 understanding on industry's part in these locations,  
19 and the Agency's part about what really HACCP is,  
20 then this is not going to be anything other than  
21 tantamount to rearranging deck chairs on the Titanic.

22           You're going to have these people having

1 these conversations, they're going to come to a point  
2 where they think it's at an impasse and the process  
3 is going to stop, and for the example of the rehang,  
4 or the scalding issue, the birds will sit outside and  
5 defecate on each other because of fecal dump, and you  
6 will have a microbiologic problem then.

7 MR. SMITH: I fully appreciate what you're  
8 saying but I also will give the flip side of that  
9 which is we get fecal contamination, we get an  
10 answer, we'll put two extra people on the line and  
11 for 15 minutes and then that's, that's the end of it.  
12 No assessment of what went wrong, no assessment of  
13 the process. If the two people were needed to  
14 establish process control, then why are the two  
15 people not there 15 minutes later?

16 If the water pressure is to be at 50 parts  
17 per million in the spray cabinet, and it's at 25 and,  
18 you know, somebody adjusted it and it's back at 50  
19 for an hour, and then you go back down and it's 35  
20 again, where's the process control?

21 That inspector is going to be forced  
22 through this system to go look at that. If the plant

1 said those things were important, that's what they're  
2 going to verify. That -- that's what the plant said  
3 they were going to do. So that's not a hazard  
4 analysis. That's what they said they were going to  
5 do and that's what they're verifying as process  
6 control. That's how I envision this working.

7 So I don't want to get into some discussion  
8 that this is theoretical. This is based on real  
9 world experience.

10 DR. YANCY: Al Yancy, U.S. Poultry. I  
11 agree, and I think in the examples you just gave,  
12 that both of those answers, unless there's proper  
13 support for them, would be ineffective. There might  
14 be a reason for two people to be there for 15  
15 minutes, and if the plant can answer that question  
16 when the Agency asks it, to the satisfaction --  
17 reasonable satisfaction of the Agency, then that  
18 should be sufficient. If not, then there are other  
19 tools that the Agency has now and that's kind of what  
20 I'm saying is the Agency has the ability and has had  
21 the ability to ask these questions all along.

22 If the purpose of this tool among other

1 things is to help give them extra support in doing  
2 that, fine, but if Agency folks don't understand that  
3 that's all this is, and they think it's the end all  
4 be all, when the answers to the questions run out or  
5 the questions run out and the dialogue needs to  
6 continue, it won't continue if that support mechanism  
7 or those support mechanisms aren't there.

8 MS. TUCKER-FOREMAN: This is Carol again.  
9 You know, again my interest is in what happens at the  
10 end of the line. Bill just talked about when you  
11 have problems that happen off and on, the process  
12 isn't under control. It's a determination that's --  
13 made. But you presume that birds that went through  
14 the line during the time the process wasn't under  
15 control are more likely to be contaminated and a risk  
16 to public health being done at the end of the line to  
17 protect the public. There is not the ongoing  
18 *Salmonella* or *Campylobacter* -- so we don't know.

19 The FDA may come in and sample the plant to  
20 see if they're meeting the *Salmonella* performance  
21 standard once a year maybe. What happens day in and  
22 day out when the plant's -- control isn't under

1 control?

2 MR. ELFERING: I think that is kind of the  
3 bottom line is what the final result of the product  
4 is, and I think in a lot of ways, they are trying to  
5 address it, Carol.

6 I think one of the questions that I had was  
7 I would want to make sure that the people who are  
8 doing this work in the plant are well-trained and  
9 well-educated and are capable of doing some critical  
10 thinking, and I think I did have a big concern about  
11 that, and I've had a number of private conversations  
12 with a number of FSIS upper management staff, and  
13 they have assured me that the people -- the  
14 inspectors who are going to be doing these tasks in  
15 the plant are going to have the training, they're  
16 going to have the educational background to do some  
17 critical thinking, and I guess I'd like that  
18 assurance from you, from the FSIS people that are  
19 here as well because I think that is a very critical  
20 part.

21 I mean you can set up a system and I mean  
22 you can train just about anybody to go out and answer

1 yes or no answers, but when those answers aren't  
2 truly there, you've got to be able to have somebody  
3 who can really understand food safety and really make  
4 some decisions and include other people, if they need  
5 to, and get other people involved, and I think that  
6 really is critical.

7 MR. SMITH: Let me answer that. This is  
8 Bill Smith, FSIS, because I don't think there's  
9 anybody in FSIS that doesn't agree with what you just  
10 said. And getting back to the point that Mr. Yancy  
11 made earlier, right, first these people have to  
12 understand how to apply these questions or this  
13 inspection method because it is an inspection method.  
14 It really does get to what, as we've said, this is  
15 nothing new 416.1s have been there forever, or at  
16 least the year 2000. And you also have another  
17 system, management control system that's seeing that  
18 the people applying the inspection method are doing  
19 it correctly, that they're documenting it, they're  
20 acting correctly and that's another management  
21 control system that has to be in tandem with this  
22 one. So there's an agreement you have to train

1 people, they have to know how to apply the method and  
2 somebody needs to check that they are applying the  
3 method, and if they're not doing it, on an ongoing  
4 basis, then you have to have a way to address that  
5 not applying the method properly in order so the  
6 industry can have confidence that the decision, the  
7 regulatory decision being made is a proper decision.  
8 And all that is part and parcel of this. So I agree  
9 with you. You just can't have a checklist and go  
10 from there, that the training, the education and the  
11 management control are all critical. This will not  
12 be successful if those others aren't there.

13 MS. TUCKER-FOREMAN: This is Carol again,  
14 and I got questions, and one of them is I think some  
15 of the people there know that I have often said if  
16 you have a constant real time sampling for *Salmonella*  
17 and *Campylobacter* at the end of the line while you  
18 run all these checks, just let the company meet the  
19 standard. How they do that may not require FSIS to  
20 have all of these prompts and details and such. If  
21 you have a mechanism contesting something at the end  
22 of the line and the plant has to make that available

1 to the Agency, these are all substitutes in my mind  
2 for the inability to test every bird or every 3rd or  
3 10th bird so that you know that what's coming off the  
4 end of the line doesn't create a health hazard for  
5 human beings.

6           And what bothers me is that too often all  
7 of these things that go on, on the line assumed a  
8 human health standard at the end of the line that we  
9 know that FSIS, we've heard it -- first of all, the  
10 *Salmonella* performance standard, the industry  
11 average, are not related to human health, and we know  
12 that the USDA does those checks literally. I think  
13 many of the plants every -- virtually -- *Salmonella*  
14 sampling that, that we don't have access to that, and  
15 we don't know that they didn't have it under control.

16           So part of my impatience to all of these  
17 prompts and all of these things that I don't see any  
18 assurance at the end of the line, that it creates  
19 something that is cleaner and safer and less likely  
20 to cause foodborne illness which was -- concern about  
21 HACCP in raw products -- HACCP interested, and you  
22 know what, it's been two years, and it's still a

1 problem. They don't have any way to tell day in and  
2 day out that the product coming off the end of the  
3 line is meeting a standard that is less likely to  
4 cause foodborne illness.

5 DR. MACZKA: The part of this process is  
6 that we -- my name is Carol Maczka. Part of this  
7 process as we will be testing for *Salmonella*, generic  
8 *E. coli* and *Campylobacter*, we're going to test for  
9 those things at post-chill and rehang. We can't just  
10 -- and then based upon the results of that, if those  
11 things are not within acceptable levels, we would  
12 move the inspector up the line to look at process  
13 control.

14 So the point is we can't test -- we can't  
15 constantly be testing the product. We can't test  
16 everything, and so -- but we need to be sure that the  
17 process is under control. So that is why we've  
18 designed the system this way. We are going to look  
19 at results from *Salmonella*, *Campylobacter*, and  
20 *E. coli*, and based upon those results, it would cause  
21 us to move up the line and look for process control.

22 MS. TUCKER-FOREMAN: But there are variable

1 animals and we just talked a few minutes ago about  
2 all of -- bird and you're assuming that process  
3 control will make that change. The USDA now does its  
4 *Salmonella* testing -- if Felicia is still there, how  
5 many times some of these plants a long time in  
6 between, a year or more -- am I supposed to assume  
7 that the process control is working day in and day  
8 out, and you don't have any data that is really up to  
9 date and that aren't again, every time I say it,  
10 human health based, they're only industry average  
11 based. You can require the plant continue to  
12 institute full daily testing, sampling on a regular  
13 basis through the day and make that information  
14 available to the USDA, I would just feel oh so much  
15 better about it. I'd like it even more if there was  
16 a human health basis through the numbers but if the  
17 companies had to do constant testing --

18 DR. ARRINGTON: Carol, Carol, this is  
19 Isabel Arrington, and I did want to mention we do  
20 have plans in the *Salmonella* initiative, we will be  
21 collecting or rather the industry will be collecting  
22 data about *Salmonella*. That will help us, give us

1 information. Also they will be collecting some  
2 *Campylobacter* data as well as some generic *E. coli*.  
3 They also are going to do this at two locations and  
4 they're also going to -- we will also have some  
5 enumeration and, of course, we will also be looking  
6 at some serotypes.

7 MS. TUCKER-FOREMAN: It's not regulatory  
8 testing. It will not go on day in and day out. Now  
9 we all know that the companies, many of them, in  
10 fact, do this. Why not require that all the  
11 companies have them so that it becomes a part of the  
12 regulatory process.

13 DR. ARRINGTON: And again, we're not  
14 talking about the regulatory *Salmonella*, although for  
15 a plant to be able to do this, they have to be in  
16 Category 1, but we are talking about that they will  
17 test on every shift and at least one sample per line  
18 on every shift.

19 MR. ELFERING: I'm going to try to get us  
20 back on track here because we need to get a report  
21 completed. So, if there's not any further comments,  
22 I think that we need to start formulating a report.

1           MR. LINK:     Kevin, can I just make one  
2 comment, and then I'll get out of your way and you  
3 can write your report.     Charles Link, Cargill.  
4 Sorry.

5           In the questions, specifically these yes,  
6 no questions, I'd encourage the Agency to go back and  
7 look at appropriate, adequate, proper, those are kind  
8 of tough question to answer yes or no. So do we have  
9 a program? Are we following the program, those kind  
10 of things, and then the second point if you just  
11 particularly look at the slaughter side and look at  
12 the scalding, you're asking very specific questions  
13 about pH control, temperature control. There's a lot  
14 of ways to manage the scalding, and it's not just pH  
15 and temperature. So when you get that specific on  
16 these questions, you're kind of almost getting us  
17 into a situation of telling us how to run the plant  
18 which is kind of tough but -- so you just need to be  
19 a little bit more broad in how you ask those  
20 questions. Thanks.

21           DR. ARRINGTON: Okay. That's very helpful.  
22 That's the kind of questions, the kind of information

1 we need to know to get at, where we want to make a  
2 determination about process control, but at the same  
3 time, we do not want to be telling the plant how they  
4 should run the plant and where they should have their  
5 controls.

6 MR. ELFERING: And that's something that we  
7 should include in our report as well. I think that  
8 is a very good point.

9 MS. TUCKER-FOREMAN: I will not, you know,  
10 again this is Carol. I'm not going to agree to the  
11 Committee doing something, coming out. You'll just  
12 have to list me as opposing the recommendation.

13 FSIS is taking us down a path -- to address  
14 a bunch of diddly issues. There is no evidence that  
15 if you're going to -- on a day in, day out basis,  
16 you're producing a product that's not going to make  
17 -- sick.

18 MR. ELFERING: We didn't really hear what  
19 you had said, Carol.

20 MS. TUCKER-FOREMAN: And nobody wants to  
21 hear that kind of comment because that fits in with  
22 their predisposition and I'm telling you that this

1 has really not worked very well over a 10 year  
2 period.

3 MR. ELFERING: Carol, maybe it would be  
4 better if, you know, on something like that, if you  
5 want to send us an e-mail again, and then -- because  
6 it's kind of difficult to really hear what you're  
7 trying to get across. So, if you could, if you want  
8 to send an e-mail to Robert Tynan, that would be very  
9 helpful.

10 MS. TUCKER-FOREMAN: Okay. But I'm not,  
11 I'm not speaking Chinese. I'm suggesting that what  
12 we need is to do away with a lot of these constant  
13 FSIS interventions in how a plant operates and shift  
14 as much as possible to a constant, constant sampling  
15 by the plant at the end of the line so they can show  
16 USDA we're producing a product that meets the public  
17 health standards and then get out of their hair.

18 MR. ELFERING: Well, I think that's  
19 certainly, you know, that's a point that's another  
20 issue that is going to need to take another time to  
21 discuss all of that because we might as well have  
22 about a week long meeting if we're, if we're going to

1 be discussing that today.

2           So I think we're going to limit it now to  
3 what the questions are in front of us. I think we've  
4 got some recommendations although I don't know if  
5 they're really what the Agency wants, and I'm not  
6 really sure what the Agency wants completely. So --  
7 but I think we've got some recommendations that we'll  
8 come up with, and I think will provide at least some  
9 guidance.

10           Why don't we take just a quick break, maybe  
11 about five minutes at the most, and then have the  
12 Committee get back and we can start putting together  
13 a written report.

14           Carol and Catherine, once we get a draft  
15 written up, we'll get it to you e-mailed as quickly  
16 as we can.

17           DR. CUTTER: Okay.

18           (Whereupon, the meeting was concluded.)

19

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1 C E R T I F I C A T E

2 This is to certify that the attached proceedings  
3 in the matter of:

4 NATIONAL ADVISORY COMMITTEE ON

5 MEAT AND POULTRY INSPECTION

6 SUBCOMMITTEE 1

7 WITHIN ESTABLISHMENT INSPECTION SYSTEM

8 Arlington, Virginia

9 February 6, 2008

10 were held as herein appears, and that this is the  
11 original transcription thereof for the files of the  
12 United States Department of Agriculture, Food Safety  
13 and Inspection Service.

14

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TIMOTHY J. ATKINSON, JR., Reporter

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